DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

CONMED Corporation
Ms. Dionne Sanders MS, RAC
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

Re: K142535
Trade/Device Name: Conmed Mixing and Delivery Kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syring
Regulatory Class: Class II
Product Code: FMF
Dated: March 13, 2015
Received: March 24, 2015

Dear Ms. Sanders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142535

Device Name
CONMED Mixing and Delivery Kit

Indications for Use *(Describe)*
The CONMED Mixing and Delivery Kit is intended for delivery of allograft, autograft, or synthetic bone graft materials to all orthopedic surgical sites. In addition, it is designed to facilitate pre-mixing of allograft, autograft or synthetic bone graft materials with IV fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CONMED CORPORATION

K142535

510(k) SUMMARY

I. SUBMITTER

CONMED Corporation
11311 Concept Blvd.
Largo, Florida 33773

Phone: 727-399-5564
Fax: 727-399-5264

Contact Person: Dionne Sanders MS, RAC
Date Prepared: April 13, 2015

II. DEVICE

Name of Device:	CONMED Mixing and Delivery Kit
Common Name:	Piston Syringe
Classification Name:	Piston Syringe (21 CFR Part 880.5860)
Regulatory Class:	Class II
Product Codes:	FMF

III. PREDICATE DEVICE

Device Name:	Arthrex Mixing and Delivery System
Company Name:	Arthrex, Inc.
510(k) #:	K121124

IV. DEVICE DESCRIPTION

The CONMED Mixing and Delivery Kit consists of a piston syringe, curved luer cannula, straight luer cannula, luer lock, obturator, and funnel. The kit is supplied as a single use, disposable kit sterilized by ethylene oxide (EtO). The kit does not include mixing material or solutions.

V. INDICATIONS FOR USE

The CONMED Mixing and Delivery Kit is intended for delivery of allograft, autograft, or synthetic bone graft materials to all orthopedic surgical sites. In addition, it is designed to facilitate pre-mixing of allograft, autograft or synthetic bone graft materials with IV fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

CONMED CORPORATION

VI. COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CONMED Mixing and Delivery Kit is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Arthrex Mixing and Delivery System, and raises no new issues of safety or effectiveness.

The similarities and differences between the predicate and proposed mixing kits are:

	Proposed Device	**Predicate Device**
	CONMED Mixing and Delivery Kit	Arthrex Mixing and Delivery System (K121124)
Manufacturer	CONMED Corporation	Arthrex, Inc.
Intended Use	For delivery of allograft, autograft, or synthetic bone graft materials to all orthopedic surgical sites. In addition it is designed to facilitate pre-mixing of allograft, autograft or synthetic bone graft materials with IV fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) and deemed necessary by the clinical use requirements.	Same
Components	1 each - piston syringe (3ml) w/movable plunger and cap, funnel, long luer cannula, curved luer cannula, luer cap, obturator	1 each – piston syringe w/movable plunger and cap (3ml or 14ml), straight delivery needle, curved delivery needle, luer cap, obturator, funnel*, articulating paddle elevator* *some components sold separately
Technological Characteristics	For mixing and delivery of allograft autograft and synthetic bone graft materials to all orthopedic sites.	Same
	18-month shelf life	5-year shelf life
	3ml syringe fill capacity	3ml or 14ml syringe fill capacity
Materials	Commonly used materials in the medical device industry	Same

VII. PERFORMANCE DATA

Testing has been completed to demonstrate that the CONMED Mixing and Delivery Kit performs as intended and is substantially equivalent to the predicate device.

Completed testing includes the following:

- Reliability
- Transportation
- Biocompatibility
- Sterilization
- Shelf-life
- Simulated Use Testing

VIII. CONCLUSION

The CONMED Mixing and Delivery Kit has the same intended use and fundamental scientific technology as the predicate device. All criteria were met during the design of the device and there were no new issues of safety or effectiveness raised. Based upon this information and the assessment of the performance data, the CONMED Mixing and Delivery Kit is substantially equivalent to the Arthrex Mixing and Delivery System (K121124).